UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

MEMORANDUM, ORDER & JUDGMENT

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In re: ZYPREXA PRODUCTS LIABILITY LITIGATION

04-MD-1596

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MOLLY GUROVITSCH,

Plaintiff,

08-CV-1408

-against-

ELI LILLY & COMPANY,

Defendant.

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JACK B.WEINSTEIN, Senior United States District Judge:

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I. Introduction

Defendant Eli Lilly & Company ("Lilly") moves for summary judgment against plaintiff Molly Gurovitsch. Plaintiff's complaint was filed in the United States District Court for the District of Minnesota. It was served on Lilly on March 4, 2008. The case was transferred to the Eastern District of New York pursuant to an order of the Judicial Panel on Multidistrict Litigation.

The action is essentially a negligence claim, based on a failure to warn. It seeks money damages for injuries, alleging that: (1) Zyprexa, an antipsychotic drug produced by Lilly, caused plaintiff's weight gain and diabetes; (2) Lilly failed to warn of the dangers of Zyprexa; and (3) Zyprexa would not have been prescribed, and adverse effects would not have been suffered, if proper warnings had been given.

For the reasons indicated below, defendant's motion for summary judgment is denied.

II. Facts

The present case is part of a massive and highly complex multidistrict litigation that has included claims by individual Zyprexa users, state attorneys general, third-party payors, and other entities alleging physical or financial injury. Some 30,000 cases have been brought against Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with Zyprexa. Like the present plaintiff, they principally allege that Zyprexa caused deleterious side effects of excessive weight gain, hyperglycemia, and diabetes; that Lilly misled them and their physicians about the likelihood of these side effects; and that, had they or their attending physicians been aware of the risks, they would not have taken Zyprexa. The court has previously

detailed the procedural history and factual background of this multidistrict litigation. *See, e.g., Mississippi v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, --- F. Supp. 2d ---, Nos. 04-MD-1596, 07-CV-645, 2009 WL 4260857 (E.D.N.Y. Dec. 1, 2009); *Blume v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-2782, 2009 WL 3596982 (E.D.N.Y. Oct. 20, 2009).

A. Contents and Use of Zyprexa

Zyprexa's active ingredient is olanzapine, one of a class of medications known as "atypical" or "second generation" antipsychotics. It was approved for use in treating schizophrenia and acute manic episodes associated with bipolar disorder by the United States Food and Drug Administration ("FDA") in 1996. In 2004, the FDA also approved Zyprexa for the treatment of bipolar disorder generally.

B. Labeling and Warnings to Patients and Medical Professionals

1. FDA Labeling and "Dear Doctor Letter"

The original 1996 Zyprexa package insert accompanying the drug disclosed information about possible side effects of administration of olanzapine based on clinical trials. The insert provided, in part, the following information:

> Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials - - Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses $\geq$ 2.5 mg/day) where the incidence in patients treated with olanzapine was greater than the incidence in placebo-treated patients.
>
> The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in

> the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studies.

Zyprexa Package Insert 11 (Oct. 1, 1996) (original emphasis).

Two tables in the insert provided the results of placebo-controlled clinical studies of olanzapine-treated patients. The data indicates that, over a six-week administration of Zyprexa, six percent of olanzapine-treated patients reported weight gain, while only one percent of the placebo-treated patients reported weight gain. *Id.* at 12-16.

For several years, this information on the insert remained substantially the same insofar as it provided physicians information on reported weight-gain-related adverse events. During this period, the results of longer-term studies and clinical experience with Zyprexa and competing drugs supporting weight gain, hyperglycemia, and diabetes became widely known. *See* Part II.B.4, *infra.*

In May 2000, the FDA undertook an analysis of the incidence of diabetes and hyperglycemia in patients using atypical antipsychotics. The director of the FDA's Division of Neuropharmalogical Drug Products requested additional safety information about Zyprexa from Lilly. In its letter, the FDA cited post-marketing reports of diabetes-related adverse events associated with Zyprexa use. In response, Lilly provided the FDA with clinical studies, data analysis, and case report reviews. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 119 (E.D.N.Y. 2008). There is disagreement about whether the information given by Lilly to the FDA was complete and accurate.

On September 11, 2003, the FDA announced it would require a warning about risks of hyperglycemia and diabetes mellitus and treating precautions to appear in the package insert of all atypical antipsychotics, including Zyprexa. Designed for prescribing doctors, the label noted that epidemiological studies and other information indicated that the relationship between the drug and hyperglycemia and diabetes was not yet fully understood. It reads as follows:

> **WARNINGS**
> **Hyperglycemia and Diabetes Mellitus**
> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomolar coma or death has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. . . .
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. . . .

Letter from Russell Katz, M.D., Dep't of Health & Human Servs., to Gregory T. Brophy, Ph.D., Eli Lilly & Co., Sept. 11, 2003, at 1-2. The label did not mention weight gain or diabetes in the "warning to patients" section.

Lilly added the FDA-required language to the Zyprexa label on September 16, 2003. *See* Zyprexa Package Insert (Sept. 16, 2003). At the FDA's request, on March 1, 2004, it sent a "Dear Doctor" letter to physicians in the United States informing them of the 2003 label change. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 134-36.

2. Consensus Statement of American Diabetes Association and Other Learned Groups

In November 2003, the American Diabetes Association, American Psychiatric Association, American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity convened a consensus development conference (the "ADA consensus conference") on the subject of the association between antipsychotic drugs and diabetes. An eight-member panel heard presentations from fourteen experts drawn from the fields of psychiatry, obesity, and diabetes, FDA representatives, and atypical antipsychotic drug manufacturers. The panel reviewed the relevant peer-reviewed English language scientific articles.

The ADA consensus conference concluded that Zyprexa and Clozaril posed an increased risk of diabetes as compared to other atypical antipsychotic drugs. The consensus statement produced by the conference declared that these relative risks as well as advantages of the drugs for individual patients in a heterogeneous population "should . . . influence drug choice." In part, its report concluded:

There is considerable evidence, particularly in patients with schizophrenia, that treatment with [atypical antipsychotics] can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after 1 year of treatment. There is, however, considerable variability in weight gain among the various [atypical antipsychotics] . . . .

***

Clozapine [Clozaril] and olanzapine [Zyprexa] . . . produce the greatest weight gain.

***

Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine [Clozaril] or olanzapine [Zyprexa] compared with patients not receiving treatment with [first generation antipsychotics] or with other [atypical antipsychotics]. The risk in patients taking risperidone and quetiapine is less clear; some studies show an increased risk for diabetes, while others do not. The two most recently approved [atypical antipsychotics], aripiprazole and ziprasidone, have relatively limited epidemiological data, but available clinical trial experience with these drugs has not shown an increased risk for diabetes.

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[T]he risks of obesity, diabetes, and dyslipidemia have considerable clinical implications in this patient population and should . . . influence drug choice.

Even for those medications associated with an increased risk of metabolic side effects, the benefit to specific patients could outweigh the potential risks. For example, clozapine [Clozaril] has unique benefits for treatment-refractory patients and those at significant risk for suicidal behavior. Since treatment response in many psychiatric conditions is heterogeneous and unpredictable, physicians and patients can benefit from the availability of a broad array of different therapeutic agents.

***

These three adverse conditions [obesity, diabetes, and dyslipidemia] are closely linked, and their prevalence appears to differ depending on the [atypical antipsychotic] used. Clozapine

> [Clozaril] and olanzapine [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia. Risperidone and quetiapine appear to have intermediate effects. Aripiprazole and ziprasidone are associated with little or no significant weight gain, diabetes, or dyslipidemia, although they have not been used as extensively as other agents.
>
> The choice of [atypical antipsychotic] for a specific patient depends on many factors. The likelihood of developing severe metabolic disease should also be an important consideration.

American Diabetes Association, et al., Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, 27 Diabetes Care 596, 596-97 (Feb. 2004)

3. FDA March 2007 Letter

On March 27, 2007, the FDA raised new concerns about the adequacy of Zyprexa's warning label in a letter to Lilly:

> [W]e are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine [Zyprexa] use . . . .
>
> Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for . . . Zyprexa provides sufficient information on these risks, and we fully intend to insure that . . . labels are enhanced with the best available information to characterize these risks.

In re Zyprexa Prods. Liab. Litig., 253 F.R.D. at 141 (quoting Letter from Thomas Laughren, FDA, to Robin Pitts Wojcieszek, Eli Lilly & Co., Mar. 27, 2007).

4. Findings on Medical Community's Knowledge of Zyprexa's Risks

A universally applicable date from which the statute of limitations is to be considered to run on an individual Zyprexa user's claim has not been determined. Numerous events represent moments at which a patient, health care provider, institution, or the medical community at large

arguably discovered that the cause of an alleged injury may have been the administration of Zyprexa. The evidence in this mass litigation, including medical records and the depositions of numerous doctors, suggests that it was widely known and understood in the late 1990s among treating and prescribing physicians that weight gain might follow the administration of Zyprexa. The association between weight gain and heightened risk of diabetes was also broadly recognized by that time.

Formal events bringing this information to the medical profession include the September 2003 Zyprexa label change and contemporaneous press release, the 2003 consensus statement of the American Diabetes Association, and the March 2004 "Dear Doctor" letter distributed nationwide to physicians by Lilly.

In its June 2007 memorandum, order, and judgment on four motions for summary judgment in individual Zyprexa injury cases, this court found that, for purposes of these motions, the March 1, 2004 "Dear Doctor" letter would be considered the latest possible date on which members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See, e.g., Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 489 F. Supp. 2d 230, 278 (E.D.N.Y. 2007). In *Souther*, applying the relevant "learned intermediary" doctrine, it was determined that Souther's claim was barred by the statute of limitations:

> Diabetes developed and Zyprexa was prescribed [to plaintiff Cusella] years before the September 2003 label change. *At least from the date of March 2004 Dear Doctor letter, the causal connection between Zyprexa and diabetes was known to Dr. Ganime, Cusella's treating physician.* Since Lilly's duty to warn ran to Dr. Gamine rather than Cusella, it became Dr. Ganime's duty from that point onwards to disclose to Cusella that Zyprexa might exacerbate his diabetes, and that it may have been the impetus behind Cusella's insulin-dependancy in the first place.

> Dr. Ganime's medical records and deposition testimony . . . show that Cusella was warned numerous times about the link between Zyprexa and diabetes. While the pre-label change warnings Dr. Ganime received from Lilly *may* not have been adequate to absolve Lilly of liability to Cusella, those warnings Cusella received from Dr. Ganime following the label change placed him on notice that use of Zyprexa might have worsened his diabetes and caused him to become insulin-dependent.
>
> *Measured either against the date Cusella developed diabetes—August 1999—or the latest possible date Dr. Gamine was aware of the potential causal connection between Zyprexa and diabetes—March 2004*—Pennsylvania's two year statute of limitations had run on Cusella's claim before he filed this suit in April of 2006.

Id. (emphases added; citations to record omitted).

The March 1, 2004 date represents the "latest possible date" prescribing physicians and, in effect, their patients are deemed aware of the potential causal connection between Zyprexa and diabetes and from which the statute of limitations may run as to any individual plaintiff. Nevertheless, a fact-specific analysis is necessary for each case to determine when the plaintiff – whether independently or by operation of the learned intermediary doctrine – knew the potential causal connection between Zyprexa and adverse health effects. The facts in many individual cases indicate a much earlier date of discovery for purposes of the statute of limitations. *See, e.g.*, Appendices A-D of *Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-1729, Docket Entries Nos. 88-1 to 88-4 (E.D.N.Y. June 11, 2007) (including relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain).

C. History and Treating Physicians' Decisions to Prescribe Zyprexa

Ms. Gurovitsch was followed for weight gain and potential metabolic problems by multiple health care professionals since before she started Zyprexa treatment in March 2001. *See*

Decl. of Paul V. Avelar ("Avelar Decl."), Ex. 20 at GUROVITSCHM_SANEK_0017, Ex. 24 at GUROVITSCHM_SANEK_0019, Ex. 25 at GUROVITSCHM_KLEINS_0026, Ex. 26 at GUROVITSCHM_KLEINS_0032, Ex. 28 at GUROVITSCHM_DICAPRIOJ_0060 to -61. Over the period during which she took Zyprexa, from March through August 2001, she gained approximately 40 pounds. *See* Aff. of Thomas J. Conlin ¶ 2 (Nov. 3, 2009). She was diagnosed with diabetes by August 16, 2001, at the latest. *See* Avelar Decl., Ex. 36 at GUROVITSCHM_ANNAP_0078 to -79.

Plaintiff began suffering from hyperactivity, impulsiveness, and tantrums at age two, and began receiving treatment for mental health issues in 1995 when she was nine. *See* Avelar Decl., Ex. 37 at GUROVITSCHM_CHC_0052. Her lengthy treatment history, including a large number of different prescription drugs and frequent medication changes, demonstrates the complexity and seriousness of her condition. *See, e.g., id.* at GUROVITSCHM_CHC_0052-70 (psychiatric evaluation and treatment history, including medication history from February 1996 through October 2001, demonstrating frequent medication changes due to lack of apparent benefit or adverse side effects). She has been described as having, at various times, attention deficit hyperactivity disorder, obsessive compulsive disorder, oppositional defiance disorder, bipolar affective disorder, and possible "tyrannical child syndrome," among other conditions. Avelar Decl., Ex. 6 at GUROVITSCHM_PASTORD_0072, Ex. 37 at GUROVITSCHM_CHC-_0054, Ex. 39 at 23, 30, 71-72. These conditions have manifested themselves in various destructive ways:

- Admissions to a psychiatric hospital. *See* Avelar Decl., Ex. 37 at GUROVITSCHM_CHC_0066.
- A wide range of mental and behavioral issues, including: frustration, rapid and drastic mood swings,

argumentativeness, fear of separation, low adaptability and challenging behaviors, significant anxiety accompanied by depressive features, obsessing about fears that she might come to harm, tactile defensiveness, impulsivity, depression, inattention, aggression, and hyperactivity. *See* Avelar Decl., Ex. 4 at GUROVITSCHM_PASTORD_0015 to -18, Ex. 7 at GUROVITSCHM_SANEK_0041.

- Placement in a special education program because of her behavior problems. *See* Avelar Decl., Ex. 8 at GUROVITSCHM_REEVEE_0183 to -87.

- Frequent outbursts of verbal abuse and violence against friends and family and an inability to accept consequences or limitations, such that she had problems with normal socialization. *See* Avelar Decl., Ex. 9 at GUROVITSCHM_PASTORD_0006, Ex. 10 at GUROVITSCHM_PASTORD_0041, Ex. 11 at GUROVITSCHM_PASTORD_0051, Ex. 12 at GUROVITSCHM_CHC_0142, Ex. 13 at GUROVITSCHM_CHC_0140.

In June of 1998, Ms. Gurovitsch began treatment with Dr. Elizabeth Reeve, a board-certified child psychiatrist, for her "extreme mood liability, obsessive-compulsive symptoms, impulsivity, decreased attention span, distractibility, irritability, and aggressive episodes." Avelar Decl., Ex. 39 at 11-12, 126, Ex. 16 at GUROVITSCHM_REEVEE_0179. Throughout the relevant time period, Ms. Gurovitsch remained "treatment refractory," meaning she was "on multiple medications, adequate doses for adequate lengths of time without adequate response." Avelar Decl., Ex. 39 at 92-93. No treatment was working. *See id.* Dr. Reeve began discussing the necessity of placing Ms. Gurovitsch in a residential treatment facility in April 2000. *See* Avelar Decl., Ex. 17 at GUROVITSCHM_REEVEE_0042. Because she "had already had acute hospital settings without success," the residential treatment facility "was a long-term placement to try to implement a more comprehensive long-term program." Avelar Decl., Ex. 39 at 85.

From August 2000 through April 2001, Ms. Gurovitsch remained at the Holcomb House residential treatment facility under the treatment of Dr. Phillip Edwardson. *See* Avelar Decl., Ex. 19 at GUROVITSCHM_REEVEE_0157 to -58, Ex. 37 at GUROVITSCHM_CHC_0066. Her medication regimes included various combinations of Seroquel, Zoloft, and Paxil. *See* Avelar Decl., Ex. 21 at GUROVITSCHM_REEVEE_0152.

On March 2, 2001, Ms. Gurovitsch was prescribed Zyprexa for the first time by Dr. Edwardson. *See* Avelar Decl., Ex. 29 at GUROVITSCHM_REEVEE_0083, Ex. 37 at GUROVITSCHM_CHC_0062. She was then fourteen years old, never having been specifically diagnosed with schizophrenia or bipolar disorder. *See* Pl.'s Memo. of Law Opposing Def.'s Mot. for Summ. J. 1 (Nov. 3, 2009). As her mother reported to Dr. Reeve in a March 13, 2001 email:

> Dr. E [ ] put Molly on [Z]yprexa and [A]xid (to counteract the side effect of weight gain). She has had a positive and amazing week or so with school, staff, and peers. I don't know if it's the meds but I'm very cautiously optimistic.

Avelar Decl., Ex. 29 at GUROVITSCHM_REEVEE_0083.

Dr. Edwards indicated in an affidavit that he was unaware of the full range of specific and relative risks posed by Zyprexa when he prescribed it for Ms. Gurovitsch:

> Based on what I had learned from Eli Lilly prior to [March 1, 2001], I believed that th[e] [Zyprexa] Patient Information Leaflet did, at the time, accurately and fairly convey the risks of the drug, and I used the leaflet to give to parents to provide information on the risks and benefits of the drug. I see now from reviewing it, however, that weight gain was listed only casually along with other side effects "that may go away during treatment," and I also see th[at] diabetes was not mentioned at all. Since the "Consensus Statement" regarding atypical antipsychotics came out in 2003, I have been careful when prescribing Zyprexa to highlight the risks of weight gain and diabetes which were either not emphasized or not included in the Patient Information Leaflet . . . .

Aff. of Phillip Edwardson, M.D. ¶ 4 (Oct. 30, 2009) ("Edwardson Aff."). After he later learned more about Zyprexa's risks, Dr. Edwards began taking additional measures to monitor and control side-effects:

> After learning more about the risks of weight gain and diabetes with Zyprexa sometime after I treated Molly Gurovitsch, I began to require that my Zyprexa patients be monitored more frequently for weight gain at two week intervals. I would then discontinue a patient from Zyprexa if the patient gained any substantial weight while using the drug.

Id. ¶ 7.

Ms. Gurovitsch remained under Zyprexa treatment for the rest of her stay at Holcomb House and was treated concurrently with Topamax, which in combination with Zyprexa is said to be used to combat weight gain. *See* Avelar Decl., Ex. 31 at GUROVITSCHM_REEVEE_0261 to -62, Ex. 39 at 130-32. A March 27, 2001 review noted that "[p]arents report that they have noted a remarkable improvement since the initiation of [Zyprexa]." Avelar Decl., Ex. 30 at GUROVITSCHM_DICAPRIOJ_0071. Her April 18, 2001 discharge summary reported that "[o]ver the course of treatment, and in particular, since the initiation of Zyprexa, Molly has made significant progress decreasing problematic behaviors related to all treatment indicators," and that "[a]s Molly has demonstrated favorable improvement in overall functioning since the instigation of Zyprexa, it is hoped that she will be able to acquire further adaptive skills." Avelar Decl., Ex. 31 at GUROVITSCHM_REEVEE_0261 to -62.

After discharge, Ms. Gurovitsch returned to the care of Dr. Reeve, who continued her Zyprexa treatment and her Topamax treatment to combat weight gain. *See* Avelar Decl., Ex. 39 at 56-57, 133-34. Dr. Reeve knew at the time "very clearly that the class of atypical

antipsychotics can cause weight gain," and that it was "common knowledge at that point already" that atypical antipsychotics had an association with development of hyperglycemia, but she could not recall "[w]hether or not [she] had formulated a specific opinion about Zyprexa causing weight gain more so than other[ ]" atypical antipsychotic medications. *Id.* at 47-48. Dr. Reeve discussed diet and exercise with Ms. Gurovitsch, and planned to decrease her Zyprexa, apparently because of weight gain concerns. *See* Avelar Decl., Ex. 32 at GUROVITSCHM_REEVEE_0011; Ex. 39 at 117-18. The risks and benefits of Ms. Gurovitsch's medications, including "the need for [weight] reduction and the possibility of PCOS [polycystic ovary syndrome] as a contributing factor," were a matter of discussion among her treating physicians. Avelar Decl., Ex. 33 at GUROVITSCHM_ANNAP_0064.

Ms. Gurovitsch's was doing "better than ever" "from the point of view of her behavior" in July 2001. *Id.* Nevertheless, at the direction of her endocrinologist, Ms. Gurovitsch's mother requested in July 2001 that she be taken off of Zyprexa "due to weight gains complicated by polycystic ovaries." Avelar Decl., Ex. 34 at GUROVITSCHM_REEVEE_0013. Dr. Reeve began tapering down Ms. Gurovitsch's Zyprexa prescriptions, with an eye towards discontinuation. *See* Avelar Decl., Ex. 35 at GUROVITSCHM_REEVEE_0010, Ex. 39 at 51-52.

Between February 21, 2001 and August 13, 2001, Ms. Gurovitsch gained 41 pounds. *See* Aff. of Thomas J. Conlin ¶ 2 (Nov. 3, 2009). By August 16, 2001, she was diagnosed with diabetes. Avelar Decl., Ex. 36 at GUROVITSCHM_ANNAP_0078 to -79. As of that date her Pediatric Diabetes Nurse Educator, Adele West, noted:

> Molly and her family are very concerned about her weight gain, which [they] attribute to some of her psychiatric medications. Currently on Zyprexa, but her psychiatrist is planning to switch her

> to [Geodon], which does not cause weight gain, if that is OK with the diabetes team.
>
> Her mother has heard that Zyprexa can cause type 2 diabetes.

Id. at 79.

III. Law

A. Summary Judgment Standard

Summary judgment is appropriate only if "there is no genuine issue as to any material fact and if the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see also Mitchell v. Washingtonville Cent. Sch. Dist.*, 190 F.3d 1, 5 (2d Cir. 1999). Dismissal is warranted when after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c); *see Anderson*, 477 U.S. at 247-50, 255; *Sledge v. Kooi*, 564 F.3d 105, 108 (2d Cir. 2009).

The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact. *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). If the moving party appears to meet this burden, the opposing party must produce evidence that raises a material question of fact to defeat the motion. *See* Fed. R. Civ. P. 56(e). This evidence may not consist of "mere conclusory allegations, speculation or conjecture." *Cifarelli v. Village of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see also Delaware & Hudson Ry. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) ("Conclusory allegations will not suffice to create a genuine issue.").

B. Choice of Law

A federal district court sitting in diversity applies the choice of law rules of the state in which it sits. *Souther v. Eli Lilly & Co.*, 489 F. Supp. 2d 230, 264 (E.D.N.Y. 2007) (citing *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487 (1941)). A multidistrict litigation transferee court applies the substantive law, including choice of law rules, of the transferor court. *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) (citing *Van Dusen v. Barrack*, 376 U.S. 612 (1964)). Because the instant action was originally commenced in the United States District Court for the District of Minnesota, that state's choice of law principles apply.

Minnesota choice of law analysis applies the substantive law of the state with the most significant relationship to the occurrence and to the parties. *See Pruett v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 07-CV-1931, 2009 WL 2245068, at *17 (E.D.N.Y. July 22, 2009) (recognizing that, under Minnesota choice of law principles, the state of "all Zyprexa use, and of any alleged resulting medical injury to plaintiff, . . . has a considerable interest in application of its law, protecting its citizens against misconduct by pharmaceutical companies," and "Minnesota's choice-influencing factors would also tilt overwhelmingly toward application of [that state's] substantive law"); *see generally Jepson v. General Cas. Co. of Wisconsin*, 513 N.W.2d 467, 469 (Minn. 1994) (Minnesota choice of law analysis looks for: first, actual conflicts; second, whether significant contacts and interests of at-issue states constitutionally permit the application of those states' laws; and third, at "five choice influencing factors set out in *Milkovich v. Saari*, 295 Minn. 155, 203 N.W.2d 408 (1973). They are: (1) predictability of result; (2) maintenance of interstate and international order; (3)

simplification of the judicial task; (4) advancement of the forum's governmental interest; and (5) application of the better rule of law.").

Minnesota's choice of law analysis results in the application of Minnesota substantive law to this action because it was filed in Minnesota, by a Minnesota resident, who received the medication in Minnesota, from Minnesota physicians, and was allegedly injured in Minnesota. Minnesota would apply its own statutes of limitation to this case because plaintiff brings Minnesota law claims. Minn. Stat. § 541.31.

C. Minnesota State Law

1. Statute of Limitations

Ms. Gurovitsch has asserted negligence and product liability causes of action. Minnesota applies a six-year statute of limitations to negligence claims and a four-year statute of limitations to product liability claims. Minn. Stat. § 541.05(1)(5) ("[T]he following actions shall be commenced within six years: . . . [any action] for any other injury to the person or rights of another, not arising on contract, and not hereinafter enumerated."); *id.* at § 541.05(2) ("Unless otherwise provided by law, any action based on the strict liability of the defendant and arising from the manufacture, sale, use or consumption of a product shall be commenced within four years."); *see Veldhuizen v. A.O. Smith Corp.*, 839 F. Supp. 669, 677 (D. Minn. 1993) (applying six year limitations period to negligence cause of action and four year limitations period to strict liability claim). Under Minnesota law, an action is not commenced until service of process, irrespective of when the complaint was filed. Minn. R. Civ. P. 3.01. A plaintiff must serve a complaint, even in federal court, within the applicable limitations period. *See Appletree Square I, Ltd. Partnership v. W.R. Grace & Co.*, 29 F.3d 1283, 1286 (8th Cir. 1994).

The parties disagree concerning when, under Minnesota law, the statute of limitations starts to run in a negligence or products liability action. Lilly asserts that Minnesota has rejected the "discovery rule," and that the statute of limitations begins to run at the time of injury, regardless of the victim's awareness or lack of awareness of the injury or its cause. *See Antone v. Mirviss*, 720 N.W.2d 331, 335 (Minn. 2006) ("We have . . . rejected the discovery rule."); *Herrmann v. McMenomy & Severson*, 590 N.W.2d 641, 643 (Minn. 1999) ("A cause of action accrues and the statute of limitations begins to run when the cause of action will survive a motion to dismiss for failure to state a claim upon which relief can be granted."); *see also Johnson v. Winthrop Labs. Div. of Sterling Drug, Inc.*, 190 N.W.2d 77, 81 (Minn. 1971) ("[I]gnorance of the existence of the cause of action does not toll the statute of limitations.").

Plaintiff asserts that Lilly has misstated Minnesota law concerning the commencement of the limitations period in negligence and products liability cases. It is noted that the *Antone* and *Herrmann* decisions, on which Lilly principally relies for rejection of the discovery rule, were both professional malpractice cases. The discovery rule is said to control in product liability and negligence actions, pursuant to a distinct line of cases applying Minnesota law. *See Klempka v. G.D. Searle & Co.*, 963 F.2d 168, 170 (8th Cir. 1992) (holding that a claim accrues when two elements are present: "(1) a cognizable physical manifestation of the disease or injury, and (2) evidence of a causal connection between the injury or disease and the defendant's product, act, or omission." (quoting *Hildebrandt v. Allied Corp.*, 839 F.2d 396, 398 (8th Cir. 1987)); *see also Edwards v. Wyeth, Inc.*, No. 07-3921, 2008 WL 1908907, at *3 (D. Minn. April 25, 2008) (statute of limitations begins to run when "a cognizable physical manifestation of the disease is

present and there is evidence of a causal connection between the disease and the defendant's product, act, or omission." (citing *Klempka*, 963 F.2d at 170)).

Professional malpractice cases limiting application of the discovery rule are not on point in this prescription drug action. It appears that plaintiff is correct that, under Minnesota law, the discovery rule applies in negligence and products liability cases. *See Klempka*, 963 F.2d at 170; *Edwards*, 2008 WL 1908907, at *3. This is consistent with the laws of many other states in the prescription drug context. *See, e.g., Belcher v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-2782, 2009 WL 3597447, at *11 (E.D.N.Y. Oct. 16, 2009) (describing California's discovery rule); *Singer v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-1338, 2009 WL 1404978, at *13 (E.D.N.Y. May 19, 2009) (describing Pennsylvania's discovery rule); *but cf. Washington v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-2592, 2009 WL 2163118, at *14 (E.D.N.Y. July 13, 2009) (Michigan does not apply the discovery rule).

2. Learned Intermediary Doctrine

The learned intermediary defense is

> an aspect of proportionality that shifts at least some of the burden of protecting patients from pharmaceutical manufacturers to treating physicians . . . . [T]he learned intermediary rule cannot be viewed as an all-or-nothing regulation that absolves the manufacturer, shifting the onus entirely to the treating physician, but its force in ameliorating liability for damages of the manufacturers cannot be ignored.

Souther, 489 F. Supp. 2d at 244. There is a strong trend in prescription drug failure-to-warn cases to reiterate and apply this well established doctrine. *See, e.g., Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (holding that a product defect claim based on insufficient warnings

cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician (citing *Plummer v. Lederle Labs., Div. of Am. Cyanamid Co.*, 819 F.2d 349, 358-59 (2d Cir. 1987)); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 780 (S.D. Tex. 2008) (granting summary judgment for defendant upon finding that prescribing physician was aware of Zyprexa's suicide-related risks that an adequate warning would have provided and that plaintiff had presented no evidence physician would not have prescribed Zyprexa had defendant provided him with an alternate warning label), *aff'd*, 321 F. App'x 350 (5th Cir. 2009); *Allgood v. GlaxoSmithKline PLC*, No. 06-3506, 2008 WL 483574, at *4 (E.D. La. Feb. 20, 2008) (granting summary judgment for defendant because prescribing doctor's "testimony clearly reveal[ed] that stronger warnings concerning the risk of suicide would not have changed his decision to prescribe"), *aff'd, sub nom. Allgood v. SmithKline Beecham Corp.*, 341 F. App'x 701 (5th Cir. 2009).

To prevail on a failure to warn claim under Minnesota law a plaintiff must show, inter alia, that "the lack of an adequate warning caused the plaintiff's injuries." *Donovan v. Bioject, Inc.*, No. C8-00-1112, 2001 WL 243096, at *3 (Minn. App. March 13, 2001) (citing *Erickson v. Am. Honda Motor Co.*, 455 N.W.2d 74, 77-78 (Minn. App. 1990)). Minnesota recognizes the learned intermediary doctrine, such that "a manufacturer does not have a duty to warn the lay public," but rather has "a duty to warn only the treating physician." *Mozes v. Medtronic, Inc.*, 14 F. Supp. 2d 1124, 1130 (D. Minn. 1998). Application of the learned intermediary doctrine bars liability when a physician is aware of the alleged risks. *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 (Minn. 1970). A claim based on insufficient warnings cannot be sustained if

the learned intermediary would not have acted differently in the presence of a different warning. *See id.*

IV. Application of Law to Facts

A. Statute of Limitations

Lilly contends that, in the absence of a "discovery rule," Ms. Gurovitsch's claims are untimely. Her claims are said to have accrued by August 16, 2001—the latest possible date of her original diabetes diagnosis—and she did not serve Lilly with her Complaint until March 4, 2008, more than six years later. On this view, even adding 167 days for class-action tolling, *see Fuller v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-2782, 2009 WL 2485829, at *15 (E.D.N.Y. July 31, 2009) (holding that Zyprexa class actions filed April 16, 2004, and dismissed November 1, 2004, resulted in 167 days of tolling), her negligence claim subject to the six-year limitations period would have been untimely as of January 30, 2008, more than a month before her complaint was served on Lilly.

Even applying the discovery rule to Ms. Gurovitsch's claims, Lilly contends that they are time-barred, based on the time when, according to Lilly, her mother knew or should have known that her daughter's injury was potentially linked to Zyprexa. Lilly further argues that it has been prejudiced by the delay in bringing this action, due to loss or destruction of relevant medical records and gaps in witnesses' memories.

Plaintiff rejects Lilly's position that there is no applicable discovery rule. It is argued that because the limitations period did not begin to run until Ms. Gurovitsch discovered the link between Zyprexa and weight gain and diabetes, both of her claims are timely. Ms. Gurovitsch testified that she never suspected Zyprexa caused her harm until she was notified in August 2007

of a possible connection between Zyprexa and her weight gain and diabetes. *See* Avelar Decl., Ex. 40 at 34-35. She maintains that her doctors had not previously informed her that Zyprexa was connected to her diabetes. *Id.* at 41, 143. She appears to have no recollection of any discussions regarding the negative side effects associated with Zyprexa. *Id.* at 150.

The court agrees with plaintiff's interpretation of Minnesota law concerning the discovery rule. *See* Part III.C.1, *supra*. Considering the fact that plaintiff was fourteen at the time Zyprexa was first prescribed, even if her mother suspected a link between Zyprexa and weight gain and diabetes at that time, it is possible that she, a mentally disturbed adolescent patient, did not. No evidence has been offered that would establish that Dr. Edwardson or Dr. Reeve understood the full scope of Zyprexa's potential side effects at that time.

This court has held that by March 1, 2004, the date of Lilly's "Dear Doctor" letter, members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See* Part II.B.4, *supra*. March 1, 2004 therefore represents the "latest possible date" prescribing physicians and, in effect, their patients are deemed aware of the potential causal connection between Zyprexa and diabetes, and from which the statute of limitations runs as to any individual plaintiff. *See id.*; *Souther*, 489 F. Supp. 2d at 278. Although Ms. Gurovitsch was a minor until August 2, 2004, under Minnesota's minor tolling statute this circumstance could only have extended statute of limitations for up to a year, until August 2, 2005. Minn. Stat. § 541.15(a); *see D.M.S. v. Barber*, 645 N.W.2d 383, 386-87 (Minn. 2002).

Applying the discovery rule to the evidence presented, a reasonable jury could find that the limitations period did not commence until the latest possible date, March 1, 2004. Applying

the 167-day class-action tolling period in Ms. Gurovitsch's favor, service of her complaint on March 4, 2008 would have been timely under both the four-year and six-year limitations periods. *See Fuller*, 2009 WL 2485829, at *15.

Despite the fact that this action was begun in 2008, more than six years after Ms. Gurovitsch's diabetes diagnosis, the court declines to apply the statute of limitations as a bar. It is for a jury to determine when the limitations period began to run, by resolving the potentially contested factual issue of when Ms. Gurovitsch or her prescribing physicians knew of the potential causal relationship between Zyprexa and her weight gain and diabetes.

B. Learned Intermediary Doctrine

The available evidence is mixed concerning the effect that an adequate warning of Zyprexa's risks might have had on the treating decisions of Ms. Gurovitsch's prescribing physicians.

Contemporaneous records of the initial prescriber, Dr. Edwardson, and his institution, Holcomb House, suggest that Dr. Edwardson was aware of at least some of the risks and benefits of Zyprexa, that he put Ms. Gurovitsch on Zyprexa because no other medication had worked for her, and that he kept her on Zyprexa—while trying to combat weight gain—because of its efficacy for her. In March, 2001, shortly after Ms. Gurovitsch began her Zyprexa treatment, her mother reported that "[s]he has had a positive and amazing week or so with school, staff, and peers. I don't know if it's the meds but I'm very cautiously optimistic." Avelar Decl., Ex. 29 at GUROVITSCHM_REEVEE_0083. Upon discharge from Holcomb House, it was reported that "[o]ver the course of treatment, and in particular, since the initiation of Zyprexa, Molly has made significant progress decreasing problematic behaviors related to all treatment indicators." Avelar

Decl., Ex. 31 at GUROVITSCHM_REEVEE_0261; *see also* Avelar Decl., Ex. 30 at GUROVITSCHM_DICAPRIOJ_0071. Ms. Gurovitsch was also treated by Dr. Edwardson with Topamax, which in combination with Zyprexa is said to be used to combat weight gain. *See* Avelar Decl., Ex. 31 at GUROVITSCHM_REEVEE_0262, Ex. 39 at 130-32.

Dr. Edwardson's affidavit, however, indicates that he may not have been fully aware at the time he prescribed Zyprexa to Ms. Gurovitsch of the risks associated with the drug. *See* Edwardson Aff. ¶ 4. He later changed his procedure for monitoring and treating Zyprexa patients, possibly supporting an inference that a different warning could have led to different treatment decisions in Ms. Gurovitsch's case. *See id.* ¶ 7.

Ms. Gurovitsch's second prescriber, Dr. Reeve, stated that she "knew very clearly that the class of atypical antipsychotics can cause weight gain" and that it "was common knowledge at that point already" that atypical antipsychotics had an association with development of hyperglycemia. Avelar Decl., Ex. 39 at 47-48. While Ms. Gurovitsch was taking Zyprexa, Dr. Reeve continued prescribing Topamax to manage weight gain. *Id.* at 130-32. Dr. Reeve testified that it "was clinically reasonable to use an atypical antipsychotic for explosive aggressive behavior that was refractory to other treatments or hadn't responded to other treatments." *Id.* at 140. Dr. Reeve continues to prescribe Zyprexa to adolescents today. *See* Avelar Decl., Ex. 39 at 16-17.

Dr. Reeve could not recall, however, whether at that time she was specifically aware of Zyprexa's higher risk of weight gain and diabetes relative to other antipsychotics. *Id.* at 47-48. Dr. Reeve stated that she "may have" "hypothetically" read and headed additional information—such as an alternative warning of Zyprexa's risks—if it had been provided to her:

Q: Okay. If Lilly had wanted to get information to you about the relative risks of Zyprexa with respect to weight gain and diabetes, in particular relative to the other atypicals, could they have gotten that information to you through the sales reps?

THE WITNESS: Yes.

Q: If you'd gotten that information, would you have paid attention to it?

THE WITNESS: I get information from lots and lots of different resources and I read some of it and I don't read some of it. And I can't respond as to whether or not I read a specific piece of information.

Q: Sure. My point was—or my question was a little bit directed more towards the scenario. Hypothetically.

A: Hypothetically if somebody gave me a piece of literature, I would hypothetically read it.

Q: You would have heeded it if it would have been information that would have been pertinent to your practice?

THE WITNESS: I may have.

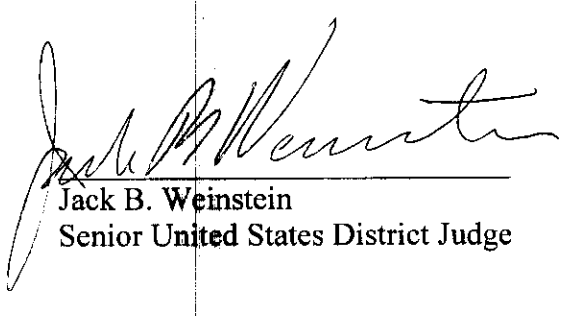
Id. at 127-128 (objections omitted); *see also*, Pl.'s Memo. of Law Opposing Def.'s Mot. for Summ. J. 12, 14 (Nov. 3, 2009).

It is appropriate for a jury to determine the significance of this evidence and the credibility and accuracy of any testimony by Dr. Edwardson and Dr. Reeve. A material factual dispute exists concerning whether a different warning by Lilly would have changed Dr. Edwardson's or Dr. Reeve's treatment decisions concerning Ms. Gurovitsch.

V. Conclusion

The motion for summary judgment against plaintiff is denied. The parties are directed to complete discovery. Once discovery is complete, plaintiff may request that the case be returned to the District of Minnesota.

SO ORDERED.



Jack B. Weinstein
Senior United States District Judge

Date: December 21, 2009
Brooklyn, New York